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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,615	08/22/2003	William J. Hennen	2820-5474.1US	8609

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
04/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/646,615	HENNEN, WILLIAM J.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,11,12,14-16,18,50,53-57 and 59-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,11,12,14-16,18,50,53-57 and 59-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed on 12/23/2009 has been received and entered into the case.

Claims 2, 3, 9, 10, 13, 17, 19-49, 51, 52 and 58 are canceled, claims 81-88 are newly added, and claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-88 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Objections

The claim objection has been withdrawn due to the amendment.

Claim Objections

Claims 50, 53-57 and 59-78 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1, 4-8, 11, 12, 14-16 and 18. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, 2nd par. (New Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 62 is not clear what subject matter the newly introduced limitation intends to point out. It is vague whether a portion of the at least one antioxidant intends to claim that the

structural portion of the antioxidant is present as a vitamin, a mineral and herb/plant extract, or the antioxidant is a part of the vitamin, the mineral and the herb/plant extract, or the antioxidant can be a vitamin, a mineral and a herb/plant extract. Clarification is required.

Claim Rejections - 35 USC § 112 - New Matter Rejection (New rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59, 62-64 and 79-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen,* 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP § 2163.06 - § 2163.07(b) for a discussion of the relationship of new matter to 35 U.S.C. 112, first paragraph.

Claim 59 introduces a new limitation of the at least one mineral comprising an LDL receptor-binding component. The specification failed to disclose any mineral being an LDL receptor-binding component. Therefore, the limitations are considered as a new matter.

In the response, Applicant alleged that magnesium lysinate is a well known mineral to bind a LDL receptor. While it is correct that lysine containing materials such as magnesium lysinate would be considered to bind a LDL receptor, it is not considered as a "mineral" per se. The binding molecule of magnesium lysinate, which is a mineral portion (magnesium) being chelated to amino acid (i.e. lysin), is lysine. Thus, it cannot be considered any mineral being a LDL receptor binding element. Rather, it appears that a LDL receptor binding molecule such as magnesium lysinate comprises a mineral.

Claim 62 introduces a new limitation directed to the at least one vitamin, the at least one mineral, and the at least one herb or plant extract of claim 50 comprising at least a portion of the at least one antioxidant. The specification appears to fail to disclose the vitamin, the mineral and the herb/plant extract comprising "a portion" of antioxidant. The specification discloses that the antioxidant can be coenyzmes, vitamins, nicotinic acid, ascorbic acid, etc. However, the specification fails to support the limitation of the vitamin, the mineral and the herb/plant extract comprising a portion of the antioxidant. It appears that this particular dependent claim to claim 50 is not necessary, and it is suggested that claim 62 is cancelled.

Claims 79 and 80 introduce a broader limitation of "at least one source" of transfer factor, which includes egg extract or colostrum extract. The specification failed to disclose a nutritional supplement "consisting of" at least one source of transfer factor (i.e. egg extract or colostrum extract) along with the listed ingredients. The original disclosure of the current application uses the broader limitation using the transitional phrase of "comprising". Since the phrase of "consisting of" changes the scope of the broader original disclosure to a narrow scope, the transitional phrase of "consisting of" in addition to the "at least one source of transfer factor" is

considered as a new matter. The exemplary composition of the specification does not disclose "at least one source of transfer factor", or egg extract or a colostrum extract as a part of ingredients present in the claimed composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-78 stand rejected under 35 U.S.C. 103(a) as being unpatentable over by Vester (of record) in view of Kirkpatrick et al. (of record), Campbell et al. (of record), Rath et al. (of record), Tentolouris et al. (of record) and Kemper (of record) in further view of Tokoro (of record).

It is noted that claims 1, 4-7, 8, 11, 12, 14-16, 18, 50, 53-57, 59-71 disclose the transitional phrase of "consisting of". However, since each of the ingredients of the composition is disclosed as genus, any ingredient which is known to belong to each genus such as vitamin, mineral, herb or plant extract, LDL receptor-binding component, blood cholesterol reduction component, blood flow-enhancing component or antioxidant is considered to be included to the claimed composition.

Vester teaches nutritional supplement for cardiovascular health. Vester teaches that minerals and/or trace elements such as magnesium, zinc, selenium, copper and potassium; vitamins A, C, E, B_6 and B_{12}; niacin (niacinamide or nicotinic acid); folate (folic acid); beta-

carotene; CoQ10, and a carrier can be components of the supplement (col. 3-5).

Vester teaches an antioxidant, flavonoids being found in numerous vegetables or fruits (col. 2, lines 34-42), and thus, flavonoids are considered as plant extract satisfying the limitation of the claimed invention. Furthermore, flavonoids are considered to be a fat oxidation prevention element (col. 3, lines 23-30).

Since the ingredients disclosed in Vester are considered as a species belongs to the claimed generic components in one way or the other (e.g. flavonoids such as quercetin of Vester being an antioxidant or a plant extract), it is considered that ingredients of Vester meet the claimed limitation.

Vester does not teach transfer factor as a component of the nutritional supplement.

Kirkpatrick et al. teach a mammalian transfer factor specific for HSV (col. 4, lines 32-37) from colostrums extract.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to combine the transfer factor specific for HSV of Kirkpatrick et al. with the nutritional supplement of Vester.

The skilled artisan would have been motivated to make such a modification because Campbell et al. teach that HSV along with other pathogens such as cytomegalovirus, H. pylori, or C. pneumoniae is associated with cardiovascular disease (p.573), and thus, a person of ordinary skill in the art would recognize that the transfer factor specific for HSV of Kirkpatrick et al. would have a benefit in treating or improving cardiovascular health.

M.P.E.P. §2144.06 states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third

composition to be used for the very same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) . See also *In re* Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) and *Ex parte* Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

Furthermore, since it is well known in the art that transfer factor can be made specific to pathogens, it would have been obvious to a person of ordinary skill in the art to use transfer factors specific for cytomegalovirus, H. pylori, or C. pneumoniae as a cardiovascular support component as Campbell et al. teach that these pathogens are associated with cardiovascular diseases (Abstract and p.573).

With regard to the lysine or lysine salt (e.g. magnesium lysinate), Rath et al. teach lysine, which binds a LDL-receptor, for treatment of cardiovascular disease (abstract). Thus, a person of ordinary skill in the art would recognize the same purpose of treating and/or improving cardiovascular health from lysine or lysine salt as the nutritional supplement of Vester in view of Kirkpatrick et al. and Campbell et al.

With regard to the arginine or arginine salt (e.g. magnesium arginate), Tentolouris et al. teach that L-arginine administration improves the coronary blood flow suggesting that L-arginine may have benefit in patients with risk factors for atherosclerosis (abstract).

It would have been obvious to a person of ordinary skill in the art to combine L-arginine or its well known salt form including arginate (e.g. magnesium arginate) of Tentolouris et al. with the nutritional supplement for cardiovascular health of Vester in view of Kirkpatrick et al., Campbell et al. and Rath et al.

With regard to the limitation drawn to the amount of transfer factor and vitamin C as in claim 72, it would have been obvious to a person of ordinary skill in the art to optimize the amount of the ingredient in the nutritional supplement of the references, since the concentration of components is considered as a result-effective variable. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Vester in view of Kirkpatrick et al., Campbell et al. Rath et al. and Tentolouris et al. do not teach that the transfer factor is non-mammalian, avian or from egg extract (claims 4-6, 53-55 and 68-71).

Tokoro teaches transfer factor from egg extract of immunized hen (see Examples).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the source of the transfer factor from mammalian as of Kirkpatrick et al. to non-mammalian (e.g. avian) from egg extract as taught by Tokoro.

The skilled artisan would have been motivated to make such a modification because the production of transfer factor in a large amount from colostrums is difficult and limited due to its production is limited to a few days, and furthermore necessitates a vast farm land according to Tokoro (see column 1, lines 39-49).

The person of ordinary skill in the art would have had a reasonable expectation of success in producing transfer factor of Kirkpatrick et al. from eggs of immunized hen since it has been successfully practiced in the art.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

In the response, Applicant alleged that Kirkpatrick teaches away from composition that include transfer factor in addition to other ingredients as such ingredients would apparently interfere with the characterization and stability of transfer factor referring col. 4, lines 49-64. This argument is not persuasive. The disclosure of Kirkpatrick cited by applicant is directed to the fact that one can obtain substantially pure transfer factor, and the inherent stability of transfer factor. There is no disclosure teaching away not to combine with other ingredients by Kirkpatrick as alleged by applicant.

Applicant further alleged that none of the references teach or suggest a composition that includes at least one mineral. This is not persuasive since Vester teaches mineral (see above).

With regard to the transfer factor specific for Chlamydia pneumoniae, cytomegalovirus or H. pylori, the cited references do not particularly teach transfer factor specific for these pathogens. However, as discussed in the claim rejection, it would have been obvious to a person of ordinary skill in the art to use transfer factor specific for these pathogens since they are known pathogens associated with cardiovascular diseases according to Campbell et al.

With regard to the limitation directed to the amount of transfer factor and vitamin C being the same amounts, applicant alleged that the OA relied on the "obvious to try" rationale. The claim rejection is based on the optimization by a routine experimentation according to

M.P.E.P. §2144.05(II), and this is not about "obvious to try" rationale of M.P.E.P. §2143(E) or the "combining prior art element" rationale of M.P.E.P. §2143(A).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651